FEB 1 0 2005

K 050220

SMDA 510(k) SUMMARY

EVIS EXERA Bronchovideoscope Olympus XBF-1T160Y3AC, XBF-160Y3AC, XBF-Q160Y2AC, its accessories and ancillary equipment

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

1. GENERAL INFORMATION

Applicant	Olympus Medical Systems Corp. 34-3 Hirai Hinode-machi, Nishitama-gun, Tokyo, 190-0182, Japan Establishment Registration No.: 3003637092
Submission Correspondent	Akiko Fukagawa Olympus Medical Systems Corp. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Phone: +81-426-2891 Fax: +81-426-3174 E-mail: akiko_fukagawa@ot.olympus.co.jp Establishment Registration No.: 8010047
Official Correspondent	Laura Storms-Tyler Director, Regulatory Affairs and Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058 Phone: 631-844-5688 Fax: 631-844-5554 Establishment Registration No.: 2429304

2. Device Identification

Trade Name:	EVIS EXERA Bronchovideoscope Olympus XBF-160Y3AC, XBF-1T160Y3AC, XBF-Q160Y2AC, its accessories and ancillary equipment
Common Name:	Bronchoscope
Regulation Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680
Class:	II
Product Code:	EOQ

3. Predicate Device

Predicate Device Name	Manufacturer	510(k) Number
EVIS EXERA Bronchovideoscope Olympus BF type 160	Olympus Corporation	K023984
EVIS EXERA Bronchovideoscope Olympus BF type 1T160	Olympus Corporation	K023984
Olympus Sterilization Trays	Olympus Winter & Ibe GMBH	K033222

4. Device Description

The subject devices, Olympus EVIS EXERA Bronchovideoscope XBF-160Y3AC, XBF-1T160Y3AC, and XBF-Q160Y2AC are identical to the predicate devices, BF-160 and BF-1T160, in intended use. These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree. As for the device specifications, they are basically identical to the BF-160 and BF-1T160 with the exception that the subject devices are now compatible with steam sterilization (autoclave) in addition to ETO gas sterilization and high level disinfection. The XBF-Q160Y2AC is loaded with higher pixels in the CCD compared to the predicate device, BF-160. The increase of the number of pixels has contributed to the expansion of image size. However, the resolution at optimum working distance of the XBF-Q160Y2AC is basically the same as that of the predicate device. Therefore, optical performance of the XBF-Q160Y2AC before and after clinical use is identical to the predicate device.
In addition to the above scopes, this submission also includes the following devices:
XMAJ-178 (Sterilization Tray)
MAJ-1214 (Water-resistant Cap)
FB-52C-1 Biopsy Forceps
FG-36D Grasping Forceps
IE-2P Magnetic Extractor
NM-8L-1 Injector
NM-9L-1 Injector
M1-1G Measuring Device
M2-1C Measuring Device
M2-2C Measuring Device

5. Intended Use of the device

EVIS EXERA Bronchovideoscope

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Accessories to the EVIS EXERA Bronchovideoscope

XMAJ-178 (Sterilization Tray)
The XMAJ-178 is a sterilization tray intended for use in medical facilities to accommodate the Olympus autoclavable Bronchovideoscopes during autoclaving.

MAJ-1214 (Water-resistant Cap)
The MAJ-1214 is attached to the electrical connector on the endoscope to protect the connector from water penetration during reprocessing.

FB-52C-1 (Biopsy Forceps)
The FB-52C-1 has been designed to be used with an Olympus endoscope to collect tissue within the thoracic and abdominal cavities and the airways and tracheobrochial tree.

FG-36D (Grasping Forceps)
This instrument has been designed to be used with Olympus endoscopes to retrieve foreign bodies, caluculi or tissue specimens from the digestive tract, urinary tract, female reproductive tract and respiratory organs.

IE-2P (Magnetic Extractor)
The Olympus IE-2P magnetic Extractor has been specially designed to be used within the airways and tracheobrochial tree.

NM-8L-1/NM-9L-1 (Injector)
These instruments have been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection within the thoracic and abdominal cavities and the airways and tracheobrochial tree.

M1-1C/M2-1C/M2-2C (Measuring Device)
These measuring devices have been designed for measuring leisions within the thoracic and abdominal cavities and the airways and tracheobochial tree.

6. Comparison of Technological Characteristics

Below is the comparison table between the subject devices and predicate device.

Specifications	Subject Device XBF-160Y3AC	Subject Device XBF-1T160Y3AC	Subject Device XBF-Q160Y2AC	Predicate Device BF-160 (K023984)
Reprocessing	ETO/Autoclaving	ETO/Autoclaving	ETO/Autoclaving	ETO
Distal end Outer Diameter	ϕ 4.9 mm	ϕ 5.9 mm	ϕ 5.5 mm	ϕ 5.3 mm
Insertion Tube Outer Diameter	ϕ 4.9 mm	ϕ 6.0 mm	ϕ 5.3 mm	ϕ 5.2 mm
Inner Channel Diameter	ϕ 2.0 mm	ϕ 2.8 mm*	ϕ 2.0 mm	ϕ 2.0 mm
CCD	94,148 pixels	94,148 pixels	253,550 pixels	94,148 pixels

*Inner Channel Diameter of XBF-1T160Y3AC is identical to that of the other predicate device, BF-1T160.

7. Materials

Biocompatibility testing was performed in accordance with Japan's Ministry of Health and Welfare notification "GUIDELINES FOR BASIC BIOLOGICAL EVALUATION OF MEDICAL DEVICES" (issued on June 27 1995), YAKKI No.99.

8. Conclusion

When compared to the predicate device, XBF-160Y3AC, XBF-1T160Y3AC and XBF-Q160Y2AC do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety and effectiveness. Therefore, clinical data is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2005

Olympus Medical Systems Corporation
c/o Ned Devine
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: K050220
Trade/Device Name: EVIS EXERA Bronchovideoscope Olympus XBF-160Y3AC, XBF-1T160Y3AC, XBF-Q160Y2AC, its accessories and ancillary equipment
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Dated: January 31, 2005
Received: January 31, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050220

Indications for Use

510(k) Number(if known):

Device Name: EVIS EXERA Bronchovideoscope Olympus XBF-160Y3AC, XBF-1T160Y3AC, XBF-Q160Y2AC, its accessories and ancillary equipment

Indications for Use:

- **EVIS EXERA Bronchovideoscope:**

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobrochial tree.

- **Accessories to the EVIS EXERA Bronchovideoscopes:**

XMAJ-178 (Sterilization Tray)
The XMAJ-178 is a sterilization tray intended for use in medical facilities to accommpdate the Olympus autoclavable Bronchovideoscopes during autoclaving.

MAJ-1214 (Water-resistant Cap)
The MAJ-1214 is attached to the electrical connector on the endoscope to protect the connector from water penetration during reprocessing.

FB-52C-1 (Biopsy Forceps)
The FB-52C-1 has been designed to be used with an Olympus endoscope to collect tissue within the airways and tracheobrochial tree.

FG-36D (Grasping Forceps)
This instrument has been designed to be used with Olympus endoscopes to retrieve foreign bodies, caluculi or tissue specimens from the respiratory organs.

IE-2P (Magnetic Extractor)

The Olympus IE-2P Magnetic Extractor has been specially designed for retrieving magnetic foreign body such as needle endoscopically. It has been designed to be used within the airways and tracheobrochial tree.

NM-8L-1/NM-9L-1 (Injector)

These instruments have been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection within the airways and tracheobrochial tree.

M1-1C/M2-1C/M2-2C (Measuring Device)

These measuring devices have been designed for measuring leisions within the airways and tracheobrochial tree.

Prescription Use ✓ OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050220

Prescription Use ✓
(Per 21 CFR 801.109)